

AR201-13415

Karen Hoffman
12/20/2001 04:29 PM

To: NCIC OPPT/DC/USEPA/US@EPA
cc:

Subject: Animal testing for HPV Cyclic Anhydrides

----- Forwarded by Karen Hoffman/DC/USEPA/US on 12/20/01 04:29 PM -----



mailto:K.Hoffman@epa.gov#msg=1201122001042904 PM

To: Rtk Chem/DC/USEPA/US@EPA
cc:
Subject: Animal testing for HPV Cyclic Anhydrides

Attached is a letter sent on behalf of the HPV Cyclic Anhydride Committee. The committee appreciates your attention in this matter.

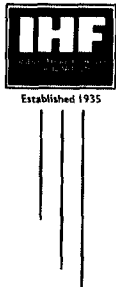
Sincerely,

Janice M. O'Polka



Project Coordinator 12-20-01 Letter to EP

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2001-10-01 10:00 AM

December 20, 2001

Christine Todd Whitman
Administrator
U.S. Environmental Protection Agency
Attn.: Chemical Right-To-Know Program
P.O. Box 1473
Merrifield, VA 22116

Re: 1101115
HPV Cyclic Anhydrides

Dear Ms. Whitman:

The Consortium on Cyclic Anhydrides was formed in good faith and in an intended spirit of cooperation with EPA's HPV program. The Industrial Health Foundation (IHF) was selected to coordinate the committee's activities and submissions. The members have a mutual interest in cyclic anhydrides and wish to avoid potentially repetitive and/or duplicative excessive testing via test rules on the five (5) chemically similar substances whose toxic properties were expected to be qualitatively similar although quantitative differences might exist. By handling these substances as a class, animal testing was intended to be substantially minimized thereby eliminating as much unnecessary animal testing as possible and still provide scientifically necessary and valid data.

The available information on these materials was assembled and considered. The data indicates that although the cyclic anhydrides are not poisons, these compounds can cause skin and respiratory sensitization and corrosive eye damage. It was noted that the Tier 1 testing package under SIDS did not suggest determination of sensitization or corrosivity potential. Therefore, it was concluded that those end points did not warrant any consideration during test plan development. To our knowledge there has been no policy statement from EPA regarding this matter.

A test plan was proposed on March 28, 2001. The test plan called for selective testing on nadic methyl anhydride, the compound of the series recognized to have the greatest oral toxicity although not a poison as defined by governmentally set criteria. EPA agreed with the proposed test program on September 20, 2001; however, the EPA did question the committee's choice of independent studies for repeat toxicity, reproductive toxicity, and/or developmental toxicity in lieu of a combined screening procedure. The combined screening procedure, OECD Method 422, had been reviewed, considered and rejected on scientific principles. The basis for the committee's decision was concern over the potential for inconclusive results which would require additional animal testing. Since this would lead to a substantial increase in the number of animals tested, a more scientific, definitive approach was suggested.

December 21, 2001

Several groups have objected to the proposed animal testing, commenting that the existing data is adequate to determine the potential hazards of the class. Due to these objections, the consortium requests that the EPA provide a written position on how recognized, significant health effects, specifically sensitization and corrosive properties of chemicals, should be used in considering the need for repeat-dose mammalian testing under the HPV program. Initiation of mammalian testing will be deferred for the present until EPA resolves the issue. The planned studies for determination of physical/chemical properties and testing for environmental fate and aquatic toxicity as originally proposed are expected to be accomplished.

The Cyclic Anhydride Consortium Registration Number is: . Please send a copy of the EPA's response to both Dr. Trochimowicz and myself. Any technical inquiries may be addressed to: Dr. Henry Trochimowicz, Sc.D., Delaware Toxicology Associates, Inc., 14 Lamatan Road, Newark, DE 19711; Phone: (302)239-4725; E-Mail: hjtroch@aol.com.

Sincerely,

Janice M. O'Polka
Project Coordinator
IHF, Inc.

cc:

Jessica T. Sandler
People for the Ethical Treatment of Animals